

K960340

ATTACHMENT 8

K960340

Summary of Safety and Effectiveness
510(k) SUMMARY

US MEDICAL PRODUCTS, INC.
CONSENSUS® Apex Dome Hole Plug (PMMA)

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Date of Preparation: 15 Dec 1995

Trade Name: CONSENSUS® Apex Dome Hole Plug

Common Name: Hip replacement prosthesis, Acetabular Shell Apex Dome Hole Plug (PMMA)

Classification Name: Class II device, under the following classification:

Prosthesis, Hip, Semi-Constrained Metal/ Polymer
classification 21 CFR 888.3350

Substantial Equivalence: equivalent Apex Dome Hole Plug (PMMA) components are as follows:

Consensus® Acetabular Cement Pods K922561 SE 07/21/93

Device Description: The Consensus® Apex Dome Hole Plug (PMMA) is intended for use with the Consensus® Total Hip System as an addition to the the metal acetabular shell and UHMWPE acetabular insert components in the Consensus® Total Hip System. It is a single use device. The Consensus® Apex Dome Hole Plug (PMMA) is designed for use with size compatible Consensus® Total Hip System components:

Porous coated Acetabular Shell	K922561	SE 07/21/93
Nonporous Acetabular Shell	K922561	SE 07/21/93
Acetabular Insert, UHMWPE	K922561	SE 07/21/93

The Concensus® Apex Dome Hole Plug (PMMA) will be provided sterile and will be available in one size. The material will be polymethylmethacrylate (PMMA), ASTM F451.

Intended Use: The CONSENSUS® Apex Dome Hole Plug (PMMA) is indicated for use in:

1. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis and avascular necrosis with a non-acute fracture of the femoral neck.
2. Osteoarthrosis involving femoral and acetabular articular surfaces.
3. Avascular osteonecrosis and/or non-union of acute femoral neck fractures.
4. Fracture-dislocation of the hip.
5. Replacement of unsatisfactory cemented or press fit hip components if sufficient bone stock exists.

Summary of Technological Characteristics: The Concensus® Apex Dome Hole Plug (PMMA), is designed function as an optional plug for the acetabular shell dome apex hole. The Concensus® Apex Dome Hole Plug (PMMA), will be provided sterile and will be available in one size. The material will be polymethylmethacrylate (PMMA), ASTM F451.

Performance Data: The Concensus® Apex Dome Hole Plug (PMMA), device performs with substantial equivalence to predicate devices.

Clinical Data: None Required

Conclusions from Non-clinical and Clinical Data: The Concensus® Apex Dome Hole Plug (PMMA), is substantially equivalent to predicate devices.

Other Necessary Information: None Required